

MANUFACTURING EXTENSION PARTNERSHIP

Success Stories from the Field

RD Medical Manufacturing

Puerto Rico Manufacturing Extension Inc

RD Medical Manufacturing Achieves ISO Certification

Client Profile:

RD Medical Manufacturing, Inc., founded in 1995, manufactures sterile and non-sterile medical devices and components. It also extrudes tubing and assembles plastic components. The company employs 80 people at its facility in Las Piedras, Puerto Rico.

Situation:

The majority of RD Medical Manufacturing's clients are medical devices manufacturers or distributors, such as Stryker, Advance Medical Optics, Pall Biomedical, and Alliance. The company recognized that obtaining ISO 13485:2003 Standard certification was essential to meet current market requirements and achieving continuous growth. RD Medical Manufacturing called upon the Puerto Rico Manufacturing Extension Inc. (PRIMEX), a NIST MEP network affiliate, to assess their quality system in order to meet the ISO 13485:2003 standard requirements.

Solution:

Upon PRIMEX's initial visit, a Gap Analysis was completed and a formal project plan was developed and initiated. PRIMEX's Performance Consultant directed the company towards the implementation of the required changes to their Quality Management System. Manuals and required documentation were revised and implemented. With PRIMEX's support, the company hired a new Quality Manager who continued with the project. Internal auditors were trained and audits were initiated. Guidance was provided for the planning and holding of management reviews in accordance with ISO 13485:2003 requirements. After completing an internal auditing cycle and holding management reviews in accordance with the standard, RD Medical Manufacturing, Inc. successfully passed the certification audit and became fully certified under the ISO 13485:2003 Standard.

Results:

- * Realized \$20,000 in cost savings.
- * Plant performance indicators estimated at \$100,000.
- * Achieved ISO certification.
- * Gained new customers.

Testimonial:

"PRIMEX's support was essential in the preparation of our company for the certification under the ISO 13485 Standard. Certification under the ISO 13485 was necessary for RD Medical, Inc. growth. We plan to continue requesting their support to make sure we continue our improvement efforts that will allow us to obtain more business and increase our labor force in Puerto Rico."

Rafael Diaz, President

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